Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DIANE K. BURNSIDE, JONATHAN S. STINSON
and PAUL F. CHOUINARD

Appeal No. 2002-1671
Application No. 08/993,985

ON BRIEF

Before COHEN, McQUADE, and NASE, Administrative Patent Judges.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49 and 51 to 67, which are all of the claims pending in this application.

We AFFIRM-IN-PART.

BACKGROUND

The appellants' invention relates generally to implantable, radially expandable medical prostheses which are referred to as stent-grafts. In particular, the invention is a self-expanding stent-graft having a bioabsorbable structural component and a permanent graft component (specification, p. 1). A copy of the claims under appeal is set forth in the appendix to the appellants' brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Kawai et al. (Kawai)	4,950,258	Aug. 21, 1990
Berg et al. (Berg)	5,464,650	Nov. 7, 1995
Fontaine et al. (Fontaine)	5,527,354	June 18, 1996
Chaikof et al. (Chaikof)	5,741,325	Apr. 21, 1998

Claims 1 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49 and 51 to 67 stand rejected under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg.

Claims 1 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49 and 51 to 67 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kawai in view of Fontaine.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the answer (Paper No. 27, mailed January 24, 2002) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 26, filed November 20, 2001) and reply brief (Paper No. 28, filed March 25, 2002) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

The obviousness rejection based on Kawai and Fontaine

We will not sustain the rejection of claims 1 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49 and 51 to 67 under 35 U.S.C. § 103 as being unpatentable over Kawai in view of Fontaine.

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, 927 F.2d 588, 591,

18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981).

In the rejection of claims 1 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49 and 51 to 67 (answer, pp. 4-5), the examiner (1) set forth the pertinent teachings of Kawai and Fontaine; (2) ascertained that Kawai lacked a graft; and (3) determined that it would have been obvious to one having ordinary skill in the art to have utilized Kawai's bioabsorbable stent with a graft as suggested by Fontaine.

Independent Claim 63

Claim 63 is directed to a stent-graft comprising, inter alia, (1) a tubular annealed structure formed of a plurality of filaments, each filament comprising bioabsorbable material; wherein the filaments include a first set of the filaments wound helically about an axis of the tubular structure and having a first common direction of winding, and a second set of the filaments wound helically about the axis and having a second common direction of winding, whereby the filaments of the second set cross the filaments of the first set at an axially directed angle; and (2) a compliant graft cooperating with at least a portion of the tubular structure to form a stent-graft adapted to be disposed in a body lumen.

The appellant argues (brief, pp. 17-18) that the above-noted crossing filament limitation of claim 63 is not taught or suggested by the combined teachings of Kawai and Fontaine as applied in the rejection before us in this appeal. We agree.[1] Clearly, the examiner has not correctly ascertained the differences between Kawai and claim 63 since Kawai does not teach the crossing filament limitation of claim 63. Moreover, the examiner has not made any determination that it would have been obvious at the time the invention was made to a person of ordinary skill in the art to have modified Kawai's bioabsorbable stent to have included crossing filaments as set forth in claim 63. Accordingly, the examiner has not established a prima facie case of obviousness with respect to claim 63 since the examiner has not found that it would have been obvious to an artisan at the time the invention was made to have modified Kawai's stent to arrive at the claimed invention. Accordingly, the decision of the examiner to reject claim 63 under 35 U.S.C. § 103 as being unpatentable over Kawai in view of Fontaine is reversed.

Claim 56

Claim 56 is directed to a stent-graft including, inter alia, (1) a structural layer comprising a bioabsorbable, radially compressible and radially self-expandable tubular body; and (2) a compliant graft layer cooperating with the structural layer to form a

[1] The examiner did not respond to this argument in the answer.

stent-graft implantable at a treatment site in a body lumen. Claim 56 further recites that (1) the structural layer is adapted to radially self-expand when deployed at the treatment site and thereby exert a radial force tending to fix the stent-graft at the treatment site and maintain patency of the body lumen; (2) the structural layer is further adapted to be absorbed in-vivo following deployment to gradually reduce the radial force; and (3) the graft layer is substantially nonabsorbable and adapted to remain at the treatment site.

The appellant argues (brief, pp. 16-17) that the stent of Kawai is not radially self-expandable as recited in claim 56 and thus the claimed subject matter is not taught or suggested by the combined teachings of Kawai and Fontaine as applied in the rejection before us in this appeal. We agree. In our view, the terms "self-expandable" and "self-expand" as used in this application and the claims under appeal clearly means that when a radially compressive force on the structural layer is released the structural layer will radially self-expand. Thus, Kawai's stent which is made from a shape-memory material which is radially compressible but requires heating to a prescribed temperature to radially expand is not radially self-expandable. Thus, the examiner has not correctly ascertained the differences between Kawai and claim 56 since Kawai does not teach the self-expandable limitation of claim 56. Moreover, the examiner has not made any determination that it would have been obvious at the time the invention was made to a

person of ordinary skill in the art to have modified Kawai's bioabsorbable stent to be self-expandable as set forth in claim 56. Accordingly, the examiner has not established a prima facie case of obviousness with respect to claim 56 since the examiner has not found that it would have been obvious to to an artisan at the time the invention was made to have modified Kawai's stent to arrive at the claimed invention. Accordingly, the decision of the examiner to reject claim 56 under 35 U.S.C. § 103 as being unpatentable over Kawai in view of Fontaine is reversed.

Claim 1

Claim 1 is directed to a stent-graft comprising, inter alia, (1) a bioabsorbable structural support comprising a radially compressible and self-expandable tubular body; and (2) a permanent graft cooperating with the structural support to provide a coextensive portion where at least a part of the coextensive portion has a length of the bioabsorbable structural support and a length of the permanent graft bonded together.

The appellant argues (brief, p. 16) that the above-noted bonding limitation of claim 1 is not taught or suggested by the combined teachings of Kawai and Fontaine as applied in the rejection before us in this appeal. We agree.[2] Clearly, the examiner has not correctly ascertained the differences between Kawai and claim 1 since Kawai does

[2] The examiner did not respond to this argument in the answer.

not teach a stent (i.e., the bioabsorbable structural support) bonded to a graft as set forth in claim. Moreover, the examiner has not made any determination that it would have been obvious at the time the invention was made to a person of ordinary skill in the art to have modified Kawai's bioabsorbable stent to be bonded to the graft as recited in claim 1. In addition, the self-expandable limitation of claim 1 is not met by Kawai for the reasons set forth above with respect to claim 56. Accordingly, the examiner has not established a prima facie case of obviousness with respect to claim 1 since the examiner has not found that it would have been obvious to to an artisan at the time the invention was made to have modified Kawai's stent to arrive at the claimed invention. Accordingly, the decision of the examiner to reject claim 1 under 35 U.S.C. § 103 as being unpatentable over Kawai in view of Fontaine is reversed.

Claims 2 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49, 51 to 55, 57 to 62 and 64 to 67

The decision of the examiner to reject dependent claims 2 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49, 51 to 55, 57 to 62 and 64 to 67 under 35 U.S.C. § 103 as being unpatentable over Kawai in view of Fontaine is also reversed for the reasons provided above with respect to their respective independent claims (i.e., claims 1, 56 and 63).

The obviousness rejection based on Chaikof and Berg

We sustain the rejection of claims 1 to 4, 6, 8 to 16, 56, 59 to 62 and 67 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg but not the rejection of claims 19 to 21, 36, 37, 39 to 49 and 51 to 55, 57, 58 and 63 to 66.

In the rejection of claims 1 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49 and 51 to 67 (answer, pp. 3-4), the examiner (1) set forth the pertinent teachings of Chaikof and Berg; (2) ascertained that Chaikof lacked the stent (i.e., the structural support) being made from a bioabsorbable material; and (3) determined that it would have been obvious to one having ordinary skill in the art to have utilized the bioabsorbable material of Berg for Chaikof's stent.

Claim 63

The appellant argues (brief, p. 12) that the limitation of claim 63 that the tubular structure (i.e., stent) is a tubular **annealed** structure is not taught or suggested by the combined teachings of Chaikof and Berg as applied in the rejection before us in this appeal. We agree.[3] The examiner has not correctly ascertained the differences between Chaikof and claim 63 since Chaikof does not teach that his tubular structure is annealed. Moreover, the examiner has not made any determination that it would have

[3] The examiner did not respond to this argument in the answer.

been obvious at the time the invention was made to a person of ordinary skill in the art to have modified Chaikof's tubular structure to be annealed as required by claim 63. Accordingly, the examiner has not established a prima facie case of obviousness with respect to claim 63 since the examiner has not found that it would have been obvious to to an artisan at the time the invention was made to have modified Chaikof's tubular structure to arrive at the claimed invention. Accordingly, the decision of the examiner to reject claim 63 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg is reversed.

Claims 19 to 21, 36, 37, 39 to 49, 51 to 55, and 64 to 66

The decision of the examiner to reject dependent claims 19 to 21, 36, 37, 39 to 49, 51 to 55, and 64 to 66 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg is reversed for the reasons set forth above with respect to their parent claim (i.e., independent claim 63).

Claim 1

The appellant argues (brief, pp. 8-12; reply brief, pp. 1-2) that the subject matter of claim 1 is not taught or suggested by the combined teachings of Chaikof and Berg. We do not agree for the following reasons.

Chaikof's invention relates to intraluminal prosthetic devices. In particular, Chaikof's invention relates to self-expanding intraluminal composite prosthetic devices for use, e.g., in endovascular applications. Chaikof teaches (column 5, lines 20-57) that

> [t]he present invention provides a true composite device that possesses the structural and mechanical reinforcing characteristics of a stent with the containment characteristics of a graft. A "composite" as used herein refers to two components, e.g., the reinforcing and sealing components that are blended rather than two devices that are attached. Blending of components can be achieved by any of a number of means including, but not limited to, interweaving the component fibers to form a composite structure.
>
> The device of the present invention consists of a mechanically stiff component that is blended with a more compliant component, the combination of which is fabricated as a straight or branched tubular structure. The stiff component provides mechanical resistance such that any radial deformation of the tube requires some force. Further, the elastic deformation characteristics of the two components can be identical such that deformation of the device (for delivery or deployment) occurs in an isotropic fashion so as to avoid internal stress gradients that may cause the two components to separate. The composite nature of the device homogeneously distributes these forces so as to minimize the possibility of device failure. This is in contrast to the assembly of two separate devices (such as a graft and a stent) where the stress is concentrated in whatever means is used to fasten the two devices together. The isotropic expansion characteristics possessed by the present invention also minimize the damage to vascular tissue that potentially occurs with other devices such as a Nitinol stent.
>
> Although braiding of the components comprises the preferred embodiment of the device, blending of any two components that possesses these consistent deformation characteristics may be used. Other possible composite systems include an expanding metal mesh protruded in a tubular form with a polymeric matrix that is subsequently cross-linked, by chemical, radiative or other means to form an elastomeric matrix with deformation characteristics consistent with those of the metal mesh.

Referring now to the figures, Chaikof's self-expanding intraluminal composite prosthesis 10 comprises an elongated tubular shaped member 2 having a body portion 4, the body portion 4 being formed by at least one layer of a composite material 6, the composite material 6 being comprised of a plurality of strands of a reinforcing fiber 8 and a plurality of strands of a sealing fiber 12. The fibers 8, 12 are interwoven, thereby forming the composite material 6. The tubular shaped member 2 has an expanded or resting diameter, a radially contracted diameter, and an operable diameter when deployed in a body passage 14 which is intermediate the expanded and radially contracted diameters, the tubular shaped member 2 being radially compressible along its longitudinal axis between the expanded and radially contracted diameters to permit intraluminal delivery of the tubular shaped member 2 through a body passage 14 to a predetermined delivery site 16. At the predetermined delivery site 16, the tubular shaped member can self-expand within the body passage 14 to its operable diameter as shown in Figures 4-5.

Chaikof teaches (column 6, lines 19-25) that "[t]he reinforcing fibers 8 can be comprised of any biocompatable material including, but not limited to, metals, polymers, organic fibers or combinations thereof. The sealing fibers 12 can be comprised of any biocompatable polymer or carbon fiber. Examples of suitable polymers include, polyethyleneterepthalate, polytetrafluoroethylene, polyurethane, polysiloxane or nylon."

Berg's invention relates to intravascular stents for treatment of injuries to blood vessels and particularly to stents having a framework onto which a therapeutic substance or drug is applied. Berg teaches (column 3, lines 29-45) that the underlying structure of the stent can be virtually any stent design, whether of the self-expanding type or of the balloon-expandable type. Berg further teaches (column 4, lines 35-53) that

> [t]he polymer chosen [for the stent] must be a polymer that is biocompatible and minimizes irritation to the vessel wall when the stent is implanted. The polymer may be either a biostable or a bioabsorbable polymer depending on the desired rate of release or the desired degree of polymer stability, but a bioabsorbable polymer is probably more desirable since, unlike a biostable polymer, it will not be present long after implantation to cause any adverse, chronic local response. Bioabsorbable polymers that could be used include poly(L-lactic acid), polycaprolactone, poly(lactide-co-glycolide), poly(hydroxybutyrate), poly(hydroxybutyrate-co-valerate), polydioxanone, polyorthoester, polyanhydride, poly(glycolic acid), poly(D,L-lactic acid), poly(glycolic acid-co-trimethylene carbonate), polyphosphoester, polyphosphoester urethane, poly(amino acids), cyanoacrylates, poly(trimethylene carbonate), poly(iminocarbonate), copoly(ether-esters) (e.g. PEO/PLA), polyalkylene oxalates, polyphosphazenes and biomolecules such as fibrin, fibrinogen, cellulose, starch, collagen and hyaluronic acid.

In applying the test for obviousness, we reach the conclusion that the combined teachings of Chaikof and Berg would have made it obvious at the time the invention was made to a person of ordinary skill in the art to have formed Chaikof's reinforcing fibers 8 (which constitute the structural support) from a bioabsorbable polymer in view of (1) Chaikof's teaching that reinforcing fibers 8 can be made from any biocompatable

material including polymers, and (2) Berg's teaching that a bioabsorbable polymer is probably more desirable than a biostable polymer since the bioabsorbable polymer will not be present long after implantation to cause any adverse, chronic local response.

The appellants' argument is unpersuasive since the claimed subject matter is suggested by the combined teachings of Chaikof and Berg for the reasons set forth above. The combined teachings of Chaikof and Berg do suggest the combination of a bioabsorbable self-expandable stent and a permanent graft since Chaikof teaches the combination of a self-expandable stent and a permanent graft while Berg's suggests making Chaikof's self-expandable stent from a bioabsorbable material. As to the appellants' argument concerning the deficiencies of each reference on an individual basis, it is well established that nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures. See In re Merck & Co. Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986).

For the reasons set forth above, the decision of the examiner to reject claim 1 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg is affirmed.

Claim 4

Claim 4 adds to parent claim 1 the limitation that the stent-graft is adapted to provide an initial radial force when implanted in a body lumen and whereby the bioabsorbable structure support is adapted to bioabsorb over time *in-vivo* with an eventual resulting decrease in radial force to the vessel wall, and the permanent graft portion adapted to substantially remain in the body lumen.

The appellants argue (brief, p. 13) that the claim 4 limitations are not met by the combination of Chaikof and Berg. We do not agree. In our view, the teachings of Chaikof and Berg as combined above with respect to claim 1 inherently met the additional limitations of claim 4. In that regard, when Chaikof's reinforcing fibers 8 are formed from a bioabsorbable polymer they are adapted to provide an initial radial force when implanted in a body lumen and are adapted to bioabsorb over time *in-vivo* which inherently results in a decrease in the radial force to the vessel wall. Additionally, Chaikof's permanent graft is adapted to substantially remain in the body lumen. The appellants have not particularly pointed out or cognitively explained why the limitations of claim 4 are not met when Chaikof's reinforcing fibers 8 are formed from a bioabsorbable polymer.

For the reasons set forth above, the decision of the examiner to reject claim 4 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg is affirmed.

Claim 56

In applying the test for obviousness, we reach the conclusion that the combined teachings of Chaikof and Berg would have made it obvious at the time the invention was made to a person of ordinary skill in the art to have formed Chaikof's reinforcing fibers 8 (which constitute the structural support) from a bioabsorbable polymer in view of (1) Chaikof's teaching that reinforcing fibers 8 can be made from any biocompatable material including polymers, and (2) Berg's teaching that a bioabsorbable polymer is probably more desirable than a biostable polymer since the bioabsorbable polymer will not be present long after implantation to cause any adverse, chronic local response.

The appellants' argument is unpersuasive since the claimed subject matter is suggested by the combined teachings of Chaikof and Berg for the reasons set forth above with respect to claims 1 and 4.

For the reasons set forth above, the decision of the examiner to reject claim 56 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg is affirmed.

Claims 57 and 58

Claim 57 adds to parent claim 56 the further limitation that the graft layer is disposed on an inside surface of the structural layer. Claim 58 adds to parent claim 56 the further limitation that the graft layer is disposed on an outside surface of the structural layer.

The appellant argues (brief, p. 13) that the limitations of claims 57 and 58 are not met by the combination of Chaikof and Berg. We agree. In that regard, the examiner has not explained either (1) how the limitations of claims 57 and 58 are met by Chaikof or (2) why it would have been obvious at the time the invention was made to a person of ordinary skill in the art to have modified Chaikof to arrive at the subject matter as set forth in claim 57 or claim 58. Accordingly, the examiner has not established a prima facie case of obviousness with respect to claims 57 and 58. Accordingly, the decision of the examiner to reject claim 57 and 58 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg is reversed.

Claims 2, 3, 6, 8 to 16, 59 to 62 and 67

Claims 2, 3, 6, 8 to 16, 59 to 62 and 67 which depend from either claim 1 or claim 56 have not been separately argued by the appellants as required in 37 CFR

§ 1.192(c)(7) and (8)(iv). Accordingly, we have determined that these claims must be treated as falling with their respective independent claim. See In re Nielson, 816 F.2d 1567, 1572, 2 USPQ2d 1525, 1528 (Fed. Cir. 1987). Thus, it follows that the decision of the examiner to reject claims 2, 3, 6, 8 to 16, 59 to 62 and 67 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg is also affirmed.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1 to 4, 6, 8 to 16, 19 to 21, 36, 37, 39 to 49 and 51 to 67 under 35 U.S.C. § 103 as being unpatentable over Kawai in view of Fontaine is reversed; and the decision of the examiner to reject claims 1 to 4, 6, 8 to 16, 18 to 21, 36 to 49 and 51 to 67 under 35 U.S.C. § 103 as being unpatentable over Chaikof in view of Berg is affirmed with respect to claims 1 to 4, 6, 8 to 16, 56, 59 to 62 and 67 and reversed with respect to claims 19 to 21, 36, 37, 39 to 49 and 51 to 55, 57, 58 and 63 to 66.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

IRWIN CHARLES COHEN Administrative Patent Judge	)
JOHN P. McQUADE Administrative Patent Judge	) BOARD OF PATENT) APPEALS) AND) INTERFERENCES
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